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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,258	01/18/2006	Arie Gijsbert Nieuwenhuizen	2001-1185-1	5993

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,258	NIEUWENHUIZEN ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-23 are presented for Examination.

Applicants' election **without traverse** of Group II claims 16-23 drawn to a method of treating and/or preventing overweight in mammal, comprising adminsitering g a preparation which comprises a flavonoids and procyanidin set forth in claim 16 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 16-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of overweight", does not reasonably provide enablement for the "prevention of overweight". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or preventing overweight in a mammal with a dosage containing an effective amount of chrysin. The nature of the invention is complex in that it encompasses the actual prevention of overweight (i.e. obesity) such that the subject treated with above compound does not develop obesity.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention of overweight in mammal, which has potentially many different causes (i.e. many different mutations or combination of mutations, hereditary, drug reaction, medical condition). Each of which may or may not be addressed by the administration of the claimed compound.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed compound to a subject in order to actually **prevent overweight** is minimal. All of the guidance provided by the specification is directed towards **treatment rather than prevention** of overweight.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of overweight.

State of the Art: While the state of the art is relatively high with regard to treatment of overweight (i.e. obesity), the state of the art with regard to **prevention** of such disorders is underdeveloped. The state of the art, Garren et al. (U.S.Patent No. 4,416,267) teaches that obesity is a major illness in the United States and other countries. It is complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, venous disease, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy. **Medical management including dietary, psychotherapy, medications and behavioral modification techniques have yielded extremely poor results in multiple trials**. Several surgical techniques have been tried but have been proven both hazardous to perform in morbidly obese patients and have been fraught with numerous life-threatening postoperative complements. (column 1, lines 10-28). To the extent that the claims are drawn to **"prevention",** it is highly speculative; a greater amount of evidence is required to show its operability in humans.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of overweight in a mammal with the claimed compound makes practicing the claimed invention unpredictable in terms of prevention of overweight.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **prevention** of overweight. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard **prevention** of overweight with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of overweight with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of overweight in a subject by administration of one of the claimed compounds.

Therefore, a method of **preventing** overweight in a mammal administering chrysin is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinery (US 2004/0077556A1) in view of Nakahara et al. (U.S.Patent No. 6,294,190 B1) further in view of Allen (U.S.Patent No. 5,480,657).

Chinery teaches composition and method for promoting weight loss and promoting appetite suppression in mammals comprising **chrysin**. (abstract, page 22 [0026]-[0283], particularly, [0277]). Chinery teaches the composition is suitable for application tot he reduction of weight of slightly overweight and grossly overweight (obese) humans. (page 7, [0063]). Chinery teaches effective amount of Chrysin (a flavonoid) ranges about 0.05mg/kg/day up to about 42.9mg/kg/day (approximately 3mg to 3000mg per day for an average-size person), which encompasses Applicants'

dosages set forth in claim 16). Chinery teaches that the composition can also include caffeine. [0314], examples 1-3).

Nakahara et al. teach that **procyanidin** is the active ingredient in an antiobesity agent. (title, abstract). Nakahara et al. teach an effective daily amount of procyanidin for suppressing and relieving obesity is from 1 to 300mg/kg/body weight. (column 20, claims 1-2). This amounts encompass and touch Applicants amounts set forth in claim 16.

Allen teaches a composition for the treatment of weight gain, e.g., obesity comprising **caffeine and dietary fiber**. (abstract, Example 2). Allen teaches the effective amount of dietary fiber is less than 1 gram. This amount encompasses and overlaps Applicants' amounts set forth in claim 23.

The claims differ from the cited references in claiming combination of chrysin, procyanidin, caffeine and dietary fiber to treat obesity. To employ combinations of chrysin, procyanidin, caffeine and dietary fiber to treat obesity or overweight conditions would have been obvious because all the components are well known individually for treating obesity. It would be expected that the combination of components would treat obesity or overweight conditions as well. One of ordinary skill in the art would have combined the antiobesity agents by known methods and that in combination, each element merely would have performed the same antiobesity activity as it did separately. The convenience of putting the compounds having the same antiobesity activity of chrysin, procyanidin, caffeine and dietary fiber together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function

and to those skilled in the art, the use of the old elements in combination would have been obvious. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references. Regarding the percentages of chrysin instant claims 18 and 19, it is a standard of practice in the pharmaceutical arts to optimize the percentages of the active agents to be employed in a pharmaceutical composition based on what is already taught as an effective amount of chrysin for the treatment of obesity taught by Chinery. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is

(571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
January 8, 2009